LONDON'S GLOBAL UNIVERSITY

Biochemical Engineering

Bioprocess Validation and Quality Control (BENG0041)

Description

The course addresses the challenge of the safe delivery to patients of biopharmaceuticals and in particular injectables. The aim of the course is to familiarise students with current validation methodology using leading edge developments with expert speakers in a workshop format. Particular focus is given to development of concepts of Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs) and Quality by Design (QbD).

Upon completion of the course, a student should be able to:

• Assess new process concepts and judge key issues to be addressed before regulatory acceptability for manufacture will be achievable

• Collect the information required and validate a process and the resources requested to manage the implementation of a stage leading to full validated status

• Communicate with validation experts

• Understand what is required by the regulatory authorities for compliance including future direction of the regulations

• Understand the implications of validation for process development

• Familiarise with current validation practice across the bioprocess industry

• Understand the role of validation and quality control in ensuring public protection

• Develop communication skills including prepare a validation plan

Key information

Year	2019/20
Credit value	15 (150 study hours)
Delivery	PGT L7, Campus-based
Reading List	View on UCL website
Tutor	Miss Chika Nweke
Term	Term 2
Timetable	View on UCL website

Assessment

Coursework: 30%
Coursework: 70%

Find out more

For more information about the department, programmes, relevant open days and to browse other modules, visit ucl.ac.uk

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